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10/539,765	02/08/2006	Michael Grant	1662.004US2	2018

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,765	GRANT, MICHAEL	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *11,18,19,21,22,29,30,34,35,37-39 and 41-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-17,20,23-28,31-33,36 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20 June 2005 and 17 April 2008* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed 17April 2008 to Office Action mailed 17 March 2008 is acknowledged and entered.

Claims Status

2. Claims 26 and 28 have currently been amended.

3. Claims 1-61 are pending.

Restriction/Election

4. Election with traverse of the invention of Group I encompassing Claims 1-42 drawn to a method to segregate pathogenic and non-pathogenic microbes and to enrich and detect a target pathogenic enterohemorrhagic, enteropathogenic or enterotoxigenic microorganism is acknowledged and entered. Also acknowledged and entered is species election of:

i. pathogenic *Escherichia coli* as listed in Claim 1;

ii. enterohemorrhagic *Escherichia coli* as listed in claims 2, 7;

iii. *Escherichia* as target microbes among those listed in Claim 1, 5;

iv. pH range of 2-4 among those listed in Claims 9-11;

v. nutritional supplement as selective agent among: antibody, antibiotic, bacteriophage, inorganic supplement, organic supplement, selenite, sorbitol, or tellurite as listed in Claims 17-23, 32-39 and 42;

vi. temperature range of about 5 °C to about 35 °C among those listed in Claims 27-30;

acetic acid as the organic acid, and hydrochloric acid (i.e., HCl) as the inorganic acid.

5. Referring to M.P.E.P. §803, the traversal is on the grounds that:

(I) restriction requirement is always optional;

(II) Search and examination of an entire application can be made without serious burden, the Examiner must examine the application on the merits, even though it includes claims to distinct/independent inventions;

(III) According to M.P.E.P. §806.04(b)species may be related inventions and need not be subject to restriction, specially when the species are claimed under a common genus, are related, applicable to the practice of restriction of species, other types of restrictions and the applicants are entitled to a reasonable number of species.

In the instant case, the inventive groups I-IV are drawn to a method and three different compositions, each composition comprised of different components and therefore the four inventions are distinguishable from each for the reasons of record at Page 3, item 7 of the Office Action mailed 17 March 2008.

As to the species restriction, it is not clear how different organisms having different taxonomical, biochemical, serological and metabolic properties from each other be generically be the same. E.g., *Shigella* and *Escherichia coli* are taxonomically two different organisms belonging to art-recognized two different genera of microorganisms. Similarly, non-pathogenic *Escherichia coli* has distinct biochemical, physical and physiological properties (e.g., inhibitory to pathogenic organisms) than the biochemical and serological properties of enterohemorrhagic *Escherichia coli* and latter organism is distinguishable from enterotoxigenic *Escherichia coli* on the basis of biochemical (e.g., sorbitol fermenter and/or MUG positive) and serological properties. Similar taxonomical, biochemical, physical, morphological and serological distinct properties distinguish other target microorganisms e.g., listed in Claim 5. Likewise, different pH, temperature, selective agents, organic and inorganic acid are physically/chemically distinguished from other pH, temperature, or selective agents and organic and inorganic acids. Thus, each of the species groups listed in Claims 1-42 are different and distinguishable from each other; unless applicant is expressly accepting on record that there is no patentable distinction from said one species to other species, and that each species is effectively functional equivalent of other species as presently listed in Claims 1-42.

In addition, the burden lies not only in the search of U.S. patents, burden also lies in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Clearly different searches and issues are involved with each group. Moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case.

Examiner has fully and carefully considered, applicant's arguments filed 17 April 2008 but does not find them persuasive because of the reasons cited *supra* and those of record on pages 2-5, items 6-12 in Office Action mailed 17 March 2008. In addition, the search for each of the distinct inventions of Groups I-IV is not co-extensive particularly with regard to the literature search. For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

Accordingly, Claims 43-61 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP §821.03. Additionally Claims 11, 18-19, 21-22, 29-30, 34-35, 37-39 and 41-42 are withdrawn from further examination as non-elected species. Furthermore, Claims 1, 5 and 7 are examined to the extent that they are related to elected species identified *supra.*

6. Claims 1-10, 12-17, 20, 23-28, 31-33, 36 and 40 are examined on merits.

Priority

7. Claim for foreign priority under 35 U.S.C. §1119 (a-d) to PCT/US03/40806 filed 19 December 2003 is acknowledged.

Information Disclosure Statement

8. The Information Disclosure Statements (i.e., IDSs) filed 20 June 2005 and 17 April 2008 respectively are acknowledged, have been made of record, considered and duly signed/initialed appropriate forms are enclosed with the instant Office Action.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

10. Claims 1-10, 12-17, 20, 23-28, 31-33, 36 and 40 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Feldsine et al. (U.S. Patent 6,379,918) in view of Bochner (U.S. Patent 6,136,554).

Claims recite a method to segregate pathogenic and non-pathogenic microbes and to enrich and detect a target pathogenic enterohemorrhagic, enteropathogenic or enterotoxigenic microorganism via incubating sample in an acidic medium at a pH between 2-4 and in temperature ranging from about 5 °C to about 35 °C in presence of a selective medium.

Feldsine et al. teach a culture medium among tryp soy broth (i.e., TSB), SOB, NZCYM, brain heart infusion, nutrient broth among others to selectively isolate/ detect presence of entero-hemorrhagenic *Escherichia coli* in presence of other pathogenic bacteria. (Abstract, Column 3, Lines 52-65; Column 4, Lines 21-24). Feldsine et al. further teach adding specific selection components (e.g., chromogens) to selectively isolate enteropathogenic organisms (e.g., *Escherichia coli*) from environmental, water and body fluid samples (Column 9, Lines 4-8 and Lines 40-45). Feldsine et al., however, do not explicitly elaborate on each and every component of each of selective culture media, media comprising specific chromogens or selective agents (e.g., tellurite, tetrathionate, sorbitol, other organic and inorganic salts) to specifically isolate *Escherichia coli* 0157:H7 isolates. Bochner teaches specific components for a variety of culture media that comprise specific selective agent, i.e., sorbitol, and inorganic and organic (e.g., proteose peptone, yeast extract, enzymes or enzyme detecting substrates) components (Abstract; Column 19, Lines 8-64; Column 22, Lines 22-59; Column 224, Lines 8-42; Column 25, Lines 5-1; Lines 54-67, Column 31, Lines 28-39; Tables 11-4 and Column 53, Lines 1-32). Note *Escherichia coli* 0157:H7 isolates encompass specifically *Escherichia* as target organism as well as pathogenic microorganism that is isolated with specific nutritional agents.

A person of ordinary skill in the art at the time the invention was made would be motivated to combine teachings from Feldsine et al., according to the teachings of Bochner to obtain a method to selectively isolate and distinguish enterohemmorrhagenic *Escherichia coli* 0157:H7 isolates; because Bochner clearly teaches specific chromogens or selective agents (e.g., tellurite, tetrathionate, sorbitol, other organic and inorganic salts) to specifically isolate *Escherichia coli* 0157:H7 isolates.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Feldsine et al., according to the teachings of Bochner; because Bochner clearly describes specific chromogens or selective agents to specifically isolate and distinguish *Escherichia coli* 0157:H7 isolates from other pathogenic microbes .

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the

invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the Contrary.

Conclusion

11. For aforementioned reasons no Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

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21 July 2008
/David M. Naff/
Primary Examiner, Art Unit 1657